Tennessee Medical Laboratory Board January 29, 2021 Full Board Meeting-Teleconference Minutes

| Meeting Date: | January 29, 2021 |
|--------------------------------|---|
| Time: | 9:04 AM CST |
| Location: | Tennessee Department of Health Division of Health Licensure and Regulations Metro Center Complex, Poplar Room, Ground Floor 665 Mainstream Drive Nashville, TN 37243 |
| Members Present: | Michael Johnson, MT-Med.Technologist Generalist/Chair Paul Fleming, MT Supervisor, Board Vice-Chair LeeAnne Briggs, MT- Med. Technologist, Educator Keisha Burnett, S.ACytotechnologist Mark A. Calarco, DO, Independent Lab Manager/Adm. Tereyo M. Cox, MT-Medical-Technologist, General Carla M. Davis, MD-Pathologist Danielle Gibson, MD-Pathologist, Non-Educator Gaye G. Jolly, MT-Hospital Administrator Jon Parham, DO Non-Pathologist Physician James A. Vaughn, MD-Pathologist Educator Patti J. Walton, MT-Hospital/Lab Mgr./Adm. Director |
| Vacant Position: | Previously appointed Board members continue to attend the meeting, for the following positions, until they are filled: Hospital Laboratory Manager Independent Laboratory Manager Cytotechnologist Medical Technologist |
| Staff Present: | Sandra S. Bogard, MT Consultant, Director Nina V. Smith, MT Consultant Administrative Office Kyonzte Hughes-Toombs, Deputy General OGC Fowlen Anders, MT Consultant/Supervisor ETRO Debbie Haggard, MT Consultant/Supervisor WTRO Susan Wilson, MT Consultant/Supervisor MTRO Susan Massey, MT Consultant/Surveyor MTRO |
| Staff Absent: | Francena Kennedy, MT Consultant/Surveyor WTRO |
| CLIA Manager/Representative: | Richard Carroll, CLIA Manager |
| Introduction of Board Members: | Board members made their introductions by roll call. |

Michael Johnson, MT Yes LeeAnne Briggs, MT Yes Tereyo M. Cox, MT Yes Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Paul Fleming, MT Yes Keisha Burnett, SA Yes Mark A. Calarco, DO Yes Carla M. Davis, MD Yes Danielle Gibson, MD Yes Jon Parham, DO Yes James A. Vaughn, MD Yes Patti J. Walton, MT Yes

Quorum:

Twelve (12) board members were present which

constitute a quorum.

Members Absent:

Lynn Stewart, Citizen Representative

Call To Order:

The meeting was called to order at 9:04 am CST by Mr. Paul Fleming, Full Board Vice-Chairman. Shortly afterward, the Board Chairman Mr. Michael Johnson

joined the meeting.

Presiding Officer:

The meeting was conducted by Mr. Johnson.

Electronic Meeting Process:

To Ensure Everyone Could Hear Each Other:

Board members responded by roll call.

Michael Johnson, MT Yes LeeAnne Briggs, MT Yes Tereyo M. Cox, MT Yes Paul Fleming, MT Yes Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Danielle Gibson, MD

Yes

Jon Parham, DO

Yes

James A. Vaughn, MD

Yes

The Board Members Identified If Anyone Is Present With Them:

Board members responded by roll call.

Michael Johnson, MT Yes LeeAnne Briggs, MT Yes

Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Danielle Gibson, MD

Jon Parham, DO

Yes

James A. Vaughn, MD

Yes

The Board Members Proceed With Electronic Meeting:

A motion to proceed with the electronic meeting was made by Ms. Walton.
Second: Dr. Gibson

Roll call vote:

Michael Johnson, MT Yes
LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Danielle Gibson, MD

Jon Parham, DO

James A. Vaughn, MD

Yes

The motion to proceed with the electronic meeting was approved.

The Board Members Determine If Matters Are Proper For A Teleconference:

A motion that the topics to be discussed are proper for a teleconference was made by Dr. Calarco.

Second: Ms. Walton

Roll call vote:

Michael Johnson, MT Yes
LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT Yes Keisha Burnett, SA Yes

| Mark A. Calarco, DO | Yes |
|---------------------|-----|
| Carla M. Davis, MD | Yes |
| Danielle Gibson, MD | Yes |
| Jon Parham, DO | Yes |
| James A. Vaughn, MD | Yes |

The motion that a teleconference meeting is appropriate for the topics to be discussed was approved.

The Board Members Receipt Of Meeting Material:

Board members responded by roll call.

| Michael Johnson, MT | Yes |
|---------------------|-------------|
| LeeAnne Briggs, MT | Yes |
| Tereyo M. Cox, MT | Yes |
| Paul Fleming, MT | Yes |
| Gaye G. Jolly, MT | Yes |
| Lynn Stewart | Not Present |
| Patti J. Walton, MT | Yes |
| Keisha Burnett, SA | Yes |
| Mark A. Calarco, DO | Yes |
| Carla M. Davis, MD | Yes |
| Danielle Gibson, MD | Yes |
| Jon Parham, DO | Yes |
| James A. Vaughn, MD | Yes |

Introduction of Health Related Boards Director:

The new Health Related Boards Director, Mr. George Darden, MPA was introduced to the Board.

Approve Minutes:

P & E Committee Meeting

A motion to approve the October 21, 2020 Personnel & Education Committee minutes was made by Dr. Burnett.

Second: Ms. Walton

Board members responded by roll call-

| LeeAnne Briggs, MT | Yes |
|---------------------|-------------|
| Tereyo M. Cox, MT | Yes |
| Paul Fleming, MT | Yes |
| Gaye G. Jolly, MT | Yes |
| Lynn Stewart | Not Present |
| Patti J. Walton, MT | Yes |
| Keisha Burnett, SA | Yes |
| Mark A. Calarco, DO | Yes |
| Carla M. Davis, MD | Yes |
| Danielle Gibson, MD | Yes |
| Jon Parham, DO | Yes |
| James A. Vaughn, MD | Yes |

The minutes were approved.

Full Board Meeting

A motion to approve the October 21-22, 2020 Board minutes was made by Ms. Walton.

Second: Dr. Gibson

Board members responded by roll call,

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Danielle Gibson, MD

Yes

Jon Parham, DO

James A. Vaughn, MD

Yes

The Board minutes were approved.

Ratification Of Initial Determinations P & E Committee Meeting:

Ms. Briggs reported the actions of the Personnel & Education Committee meeting, January 28, 2021.

Motion to ratify Committee actions: Dr. Vaughn Second: Dr. Davis

occorra. Dr. Davis

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Danielle Gibson, MD

Jon Parham, DO

James A. Vaughn, MD

Yes

Report: Accepted as presented by Ms. Briggs.

Contested Cases:

No contested cases were presented during this meeting.

Consent, Agreed, Compliance Orders, And Letters of Reprimand:

No consent, agreed, or compliance orders were presented during this meeting. No letters of reprimand were presented.

Presentations To The Board:

Tennessee Professional Peer Assistance Program (TNPAP) Teresa Phillips, Acting Executive Director The statistical report for July 1, 2020-December 31, 2020 was presented by Ms. Teresa Phillips, Acting Executive Director.

Zero (0) individuals were monitored during this period.

Motion to accept the TNPAP report: Dr. Gibson Second: Ms. Briggs

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT Yes
Keisha Burnett, SA Yes
Mark A. Calarco, DO Yes
Carla M. Davis, MD Yes
Danielle Gibson, MD Yes
Jon Parham, DO Yes
James A. Vaughn, MD Yes

The report was accepted as given:

Note: Review of TNPAP materials via the internet counts as clock hours toward continuing education credits.

A certificate of completion documenting the review of these materials can be completed at the end of the session. Internet site: www.TNPAP.org

Ms. Leonard's investigative report included the following:

Monitored Practitioners (Personnel and Facilities): (2020)

Four suspensions, one expired, and two currently under Board order.

Investigations ReportLori L. Leonard
Disciplinary Coordinator

Tennessee Medical Laboratory Board January 29, 2021

Investigative Licensed Laboratory Personnel: (2020)
One new complaint:
one for unprofessional conduct.

Five complaints closed:

one sent on to OGC.
one closed with no action.
two with a letter of concern.
one closed due to insufficient evidence.

Investigative Licensed Laboratory Facilities: (2020)
One new complaint:
 one for unqualified personnel.
Four complaints closed:
 one closed with no action.
 three closed due to insufficient evidence.

Investigative Licensed Laboratory Personnel: (2021) One new complaint.

Investigative Licensed Laboratory Facilities: (2021) Zero new complaints.

Motion to Accept Report: Ms. Walton Second: Dr. Calarco

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes
Lynn Stewart Not Present

Patti J. Walton, MT Yes
Keisha Burnett, SA Yes
Mark A. Calarco, DO Yes
Carla M. Davis, MD Yes
Danielle Gibson, MD Yes
Jon Parham, DO Yes
James A. Vaughn, MD Yes

The investigations report was accepted as given.

The Board Chairman, Mr. Michael Johnson, handed the gavel over to the Vice-Chairman, Mr. Paul Fleming.

Presiding Officer:

Point of Care Exemptions 1200-06-03-.16(1):

Sumner Regional Medical Center
 555 Hartsville Pike
 Gallatin, TN 37066
 Michael Johnson, MBA, MT(ASCP)
 Assistant Administrator and Admin. Director of Laboratory Services

The first request was to permit Respiratory Therapists to perform pH, PO2, PCO2, Na, K, Chloride, CO2, BUN, Creatinine, Glucose, Lactate, Hemoglobin, Hematocrit, and calculated parameters facility-wide utilizing the Siemens EPOC instrument and methodology.

Motion: Ms. Walton Second: Ms. Briggs

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Michael Johnson, MT Abstain
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Danielle Gibson, MD

Jon Parham, DO

James A. Vaughn, MD

Yes

The exemption request was approved.

The second request was to permit Registered Nurses and Certified Registered Nurse Anesthetists to perform pH, PO2, PCO2, Na, K, Chloride, CO2, BUN, Creatinine, Glucose, Lactate, Hemoglobin, Hematocrit, and calculated parameters in Intensive Care Units and Surgical Services (PACU & OR) utilizing the Siemens EPOC instrument and methodology.

Motion: Dr. Gibson Second: Dr. Davis

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Michael Johnson, MT Abstain
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT Yes Keisha Burnett, SA Yes Mark A. Calarco, DO Yes

Carla M. Davis, MD Yes
Danielle Gibson, MD Yes
Jon Parham, DO Yes
James A. Vaughn, MD Yes

The exemption request was approved.

The third request was to permit Imaging Personnel to perform Creatinine and calculated GFR in SRMC Imaging Department, Sumner Station Diagnostic Imaging Department, and Radiation Oncology utilizing the Siemens EPOC instrument and methodology.

Motion: Ms. Walton Second: Dr. Calarco

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Michael Johnson, MT Abstain
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Danielle Gibson, MD

Yes

Jon Parham, DO

Yes

James A. Vaughn, MD

Yes

The exemption request was approved.

The request to permit licensed nurses and licensed paramedics working in the VUMC Adult Emergency Department to perform Influenza A/B and SARS-CoV-2 testing on the Roche Liat analyzer.

Motion: Ms. Walton Second: Mr. Fleming

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT Yes Keisha Burnett, SA Yes

2. Vanderbilt University Medical Center

Nashville, TN 37232

4605 TVC, 1301 Medical Center Drive

Judy Davis, MA, MLS(ASCP), DLM, QLC

Director-Quality/Compliance/POCT

Mark A. Calarco, DO Yes
Carla M. Davis, MD Yes
Danielle Gibson, MD Yes
Jon Parham, DO Yes
James A. Vaughn, MD Yes

The exemption request was approved:

 Parkridge East Hospital Lab 941 Spring Creek Road Chattanooga, TN 37412 Von Stacy, Administrative Lab Director The request was to permit licensed Respiratory
Therapists to perform pH, PO2, PCO2, Hematocrit, Na, K,
Ca, and Glucose testing in the Neonatal Intensive Care
Unit, Labor & Delivery, and Transport Unit utilizing the
Siemens EPOC instrument and methodology.

Motion: Dr. Vaughn Second: Dr. Gibson

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Abstain
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Danielle Gibson, MD

Jon Parham, DO

James A. Vaughn, MD

Yes

The exemption request was approved.

 Parkridge Medical Center Blood Gas Laboratory
 McCallie Avenue Chattanooga, TN 37404 The request was to permit licensed Respiratory
Therapists to perform Arterial Blood Gases facility-wide
utilizing the Siemens EPOC instrument and
methodology.

Motion: Ms. Walton Second: Dr. Parham

Board members responded by roll call.

LeeAnne Briggs, MT Yes Tereyo M. Cox, MT Yes

Paul Fleming, MT Abstained

Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT Yes
Keisha Burnett, SA Yes
Mark A. Calarco, DO Yes
Carla M. Davis, MD Yes
Danielle Gibson, MD Yes
Jon Parham, DO Yes
James A. Vaughn, MD Yes

The exemption request was approved.

Direct More Than Three (3) Labs 1200-06-03-.13(5):

Nothing to present.

Discuss, Review, And Take Action, if Needed:

Governor's Executive Orders

Governor Lee's Executive Order 73 was reviewed by the Board.

Update on Task Force to discuss Digital Imaging and Remote Work

The Board provided the following objectives for the Task Force to address:

- What are the responsibilities of a medical director while working remotely?
- How to regulate remote lab work that includes:
 - 1. Cytogenetics (FISH)
 - 2. Pathology
 - 3. Flow cytometry
- Identify any issues with pathologists using digital imaging to read clinical slides.
- Where is the diagnosis rendered?
- If testing is performed in a home, is it subject to inspection?
- What is the impact on pathologists that read in multiple locations?
- How will remote work be regulated and how will oversight take place?

No motion was needed.

Discuss the Addition of Specialties to an Esoteric Laboratory License Resolve Molecular Diagnostics-Esoteric Lab Franklin, TN David L. Smalley, PhD-Laboratory Director The Board discussed specialties for SARS-CoV-2 testing as they pertained to esoteric laboratories. The COVID-19 State Licensure Test Specialties for Esoteric Labs List was revised to reflect:

 Molecular PCR Test: Esoteric-Molecular Diagnostics (Specialty)

- Antibody Test: Determined to not be an esoteric test.
- Antigen Test: Determined not to be an esoteric test.

Based on Governor Lee's current Executive Order, esoteric laboratories can perform antigen and/or antibody SARS-CoV-2 testing without the addition of any new specialties. The labs must notify the Medical Laboratory Board's Administrative Office of the addition to their test menu. The Administrative Office will maintain a spreadsheet of all laboratories performing SARS-CoV-2 testing. Once the Executive Order expires, any esoteric lab that wishes to continue performing the antigen and/or antibody SARS-CoV-2 test must apply for a clinical laboratory license.

The Board requested that esoteric laboratories that are submitting an initial lab application or addition of specialty request must appear before the Board. A request was also made for a policy statement to be drafted concerning esoteric labs and SARS-CoV-2 testing.

No motion was needed.

The Board discussed mobile laboratory testing. Mobile laboratory testing was defined as testing that takes place on a vehicle. The transporting of equipment to a specific location and setting up equipment does not constitute a mobile lab. It is considered a health screening. Mobile labs can perform testing at any complexity level. A hospital or a reference lab would need to serve as the home base for a mobile laboratory. The Board did not set any limits on how often the mobile lab would need to dock at its home base. If the mobile lab crosses state lines, it would be subject to the laws of that state. The laboratory personnel on the mobile lab must be Tennessee state licensed. The laboratory director and laboratory supervisor can reside at the home base. The laboratory license of the home base must be current and include the specialties for the testing performed at the permanent location as well as the mobile lab. Mobile labs will be subject to inspections by the state laboratory surveyors.

The Board did recommend that mobile labs obtain adequate commercial grade insurance in the event of an automotive accident. Also, the mobile lab would need

Discuss Mobile Laboratory Testing Expertus Health LLC-Perry Community Hospital Lab Mr. Jason Weil, Owner

to ensure all HIPAA sensitive documents are secured.

A request was also made for a policy statement to be drafted concerning mobile laboratories.

Perry Community Hospital mobile lab was informed that they could test under the Governor's current Executive Order #73 provided they reactivate their hospital's lab license and add the appropriate laboratory specialties to their facility license to cover the testing that will be performed on the mobile lab.

No motion was needed.

Discuss Health Screenings by Reference Labs EDP Biotech Corporation Michael Weis, MT(ASCP)-Lab Testing Supervisor The Board discussed reference laboratories performing health screenings. Based on Governor Lee's current Executive Order, reference laboratories can perform health screenings provided the testing is for SARS-CoV-2 and written notification is submitted to the Board's Administrative Office. After the Executive Order has expired, a reference lab would need to partner with a for-profit hospital, not-for-profit organization, or submit a point-of-care exemption request for Board review to offer a health screening to the public.

No motion was needed.

Review And Discuss The Licensure Of Medical Laboratory Directors:

 Heather Glasgow, PhD Seattle, WA 98105 Director: Microbiology Dr. Glasgow received her BA degree in Molecular and Cell Biology from the University of California, Berkeley, CA in 2008.

She received her Ph.D. in Biomedical Sciences from the University of California, San Diego, CA in 2015.

Dr. Glasgow is certified by the American Board of Medical Microbiology (ABMM) through Dec. 31, 2023.

She received her postdoctoral fellowship training in Clinical and Public Health Microbiology at the University of Washington in Seattle, WA from July 1, 2018-June 30, 2020.

Dr. Glasgow is seeking licensure as a Director of Microbiology.

Motion: Dr. Calarco

Second: Dr. Davis

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes
Lynn Stewart Not Present

Patti J. Walton, MT Yes
Keisha Burnett, SA Yes
Mark A. Calarco, DO Yes
Carla M. Davis, MD Yes
Danielle Gibson, MD Yes
Jon Parham, DO Yes
James A. Vaughn, MD Yes

The license was approved.

 Jeffrey Wisotzkey, PhD Athens, AL 35613
 Director: Molecular Diagnostics Dr. Wisotzkey received his BS degree in Biology from Delaware Valley College, Doylestown, PA in 1985.

He received his Ph.D. in Molecular Biology from the University of Houston in Houston, TX in 1990.

Dr. Wisotzkey is certified by the American Board of Bioanalysis (ABB) as an HCLD in Molecular Diagnostics through December 31, 2021.

His post-doctoral fellowship was completed at Jake Gittlen Cancer Research Institute and Pennsylvania State University's Hershey Medical Center in Hershey, PA from 1990-1995.

Dr. Wisotzkey is seeking licensure as a Director of Molecular Diagnostics.

Motion: Dr. Calarco Second: Ms. Briggs

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT Yes Keisha Burnett, SA Yes

Mark A. Calarco, DO Yes
Carla M. Davis, MD Yes
Danielle Gibson, MD Yes
Jon Parham, DO Yes
James A. Vaughn, MD Yes

The license was approved.

 Sandeep Mukherjee, PhD Nashville, TN 37217 Director: Molecular Diagnostics Dr. Mukherjee received his BS and MS degrees from the University of Calcutta, Kolkata, India in Chemistry in 1991 and Biochemistry (specialization in Microbiology) in 1993 respectively.

He received his Ph.D. in Molecular Biology from Jadavpur University in West Bengal, India in 1999.

Dr. Mukherjee is certified by the American Board of Clinical Chemistry (ABCC) in Molecular Diagnostics through Dec. 31, 2023.

He received his postdoctoral fellowship training in Infectious Diseases at the University of Washington in Seattle, WA from 1999-2001 and PathGroup in Nashville, TN from 2014-2021.

Dr. Mukherjee is seeking licensure as a Director of Molecular Diagnostics.

Motion: Dr. Vaughn Second: Dr. Parham

Board members responded by roll call.

LeeAnne Briggs, MT Yes Tereyo M. Cox, MT Yes

Paul Fleming, MT Abstained

Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Panielle Gibson, MD

Yes

Jon Parham, DO

James A. Vaughn, MD

Yes

The license was approved.

Katrin Hacke, PhD
 Brentwood, TN 37027
 Director: Histocompatibility

Dr. Hacke received her BS and MS degrees in Chemistry from the Technical University of Darmstadt, Germany in 1999 and 2003 respectively.

She received her Ph.D. in Pharmacy from Ruprecht-Karls-University in Heidelberg, Germany in 2007.

Dr. Hacke is certified by the American Board of Histocompatibility and Immunogenetics (ABHI) as a Diplomate through Dec. 31, 2022.

She received her postdoctoral fellowship training at the American Society of Histocompatibility and Immunogenetics (ASHI) approved Director-in-Training fellowship program at Vitalant HLA Laboratory, Mather, CA 2017-2020.

Dr. Hacke is seeking licensure as a Director of Histocompatibility.

Motion: Dr. Calarco Second: Dr. Vaughn

Board members responded by roll call.

LeeAnne Briggs, MT Yes Tereyo M. Cox, MT Yes Paul Fleming, MT Yes Gaye G. Jolly, MT Yes Lynn Stewart Not Present Patti J. Walton, MT Yes Yes Keisha Burnett, SA Mark A. Calarco, DO Yes Carla M. Davis, MD Yes Danielle Gibson, MD Yes

Jon Parham, DO Yes James A. Vaughn, MD Yes

The license was approved.

Reports/Requests:

Board Director's ReportSandra Bogard, MS, MT(ASCP) QLC ^{cm}

The report included statistical data concerning the licensure of laboratory personnel, facilities, training programs licensure, and health fair/health screening events during the third quarter.

The website continues to be updated daily/or as needed.

Staffing updates:

- New Middle TN Surveyor, Susan Massey, started on December 20, 2020.
- New West TN Surveyor, Francena Kennedy, started on January 19, 2021.

Board meeting dates for 2021 were presented.

Board terms that expired in December:

- Hospital Laboratory Manager-Ms. Patti Walton
- Independent Laboratory Manager-Dr. Mark Calarco
- Cytotechnologist-Dr. Keisha Burnett
- Medical Technologist-Ms. Tereyo Cox

The continued attendance by these Board Members, pending new appointments, is greatly appreciated.

A copy of this report is kept on file in the administrative office.

Motion to approve the report as given: Ms. Walton Second: Dr. Calarco

Board members responded by roll call,

Yes LeeAnne Briggs, MT Tereyo M. Cox, MT Yes Yes Paul Fleming, MT Gaye G. Jolly, MT Yes Lynn Stewart Not Present Patti J. Walton, MT Yes Keisha Burnett, SA Yes Mark A. Calarco, DO Yes Carla M. Davis, MD Yes Danielle Gibson, MD Yes Jon Parham, DO Yes

The report was accepted as given.

James A. Vaughn, MD

Counsel Hughes-Toombs gave her report for the past quarter:

Yes

One (1) open case is currently in the Office of General Counsel.

Board Attorney Report Kyonzté Hughes-Toombs Deputy General Counsel

The personnel rule revisions are near the end of the process and are being reviewed by the Chief Deputy's Office.

Motion to accept the report as given: Ms. Briggs

Second: Dr. Calarco

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Danielle Gibson, MD

Jon Parham, DO

James A. Vaughn, MD

Yes

The report was accepted as given.

Addition/Deletion to the Board's Waived Test List:

 Middle Tennessee Mental Health Institute
 Quidel Sofia 2 SARS-CoV-2 Antigen FIA
 The request by Middle Tennessee Mental Health Institute to perform the Quidel Sofia 2 SARS-CoV-2 antigen test was presented to the Board. This facility is currently licensed by the Tennessee Department of Health Mental Health and Substance Abuse Services. This licensure restricts their lab test menu to the Board's Waived Test list. The Board discussed revising the State Waived Test List and include all the CLIA waived tests on the state list.

Motion: Ms. Walton Second: Mr. Fleming

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT Yes Keisha Burnett, SA Yes

| Mark A. Calarco, DO | Yes |
|---------------------|-----|
| Carla M. Davis, MD | Yes |
| Danielle Gibson, MD | Yes |
| Jon Parham, DO | Yes |
| James A. Vaughn, MD | Yes |

The motion was approved.

2. Delta Specialty Hospital BD Veritor SARS-CoV-2 Antigen The request by Delta Specialty Hospital to perform BD Veritor SARS-CoV-2 antigen test was presented to the Board. This facility's lab license contains the modifier, "TN/MLB Waiver and Exempted POC Tests". The facility requested the Board consider adding the BD Veritor SARS-CoV-2 antigen test to the State's Waived Test list. Previously during this meeting, the Board approved all CLIA waived tests to be included on the State's Waived Test list. Since the BD Veritor SARS-CoV-2 antigen test is CLIA waived there was no action needed by the Board.

Regional Surveyor Reports:

Complaint Investigations Proficiency Testing Events Regional Offices: East, Middle, West TN

ETRO Report: 4th Quarter Fowlen Anders, MT Consultant/Surveyor

East Tennessee Regional Office –Fourth Quarter 2020

Complaint Investigations: One (1) closed

Unsuccessful Proficiency Testing: Zero (0)

- First Occurrence (two in a row or two out of three unsatisfactory scores: Zero (0)
- Second Occurrence (three in a row or three out of five unsatisfactory scores: Zero (0)

MTRO Report: 4th Quarter Susan Wilson, MT Consultant/Surveyor Middle Tennessee Regional Office –Fourth Quarter 2020

Complaint Investigations: One (1) unsubstantiated

Unsuccessful Proficiency Testing: One (1)

- First Occurrence (two in a row or two out of three unsatisfactory scores: One (1)
- Second Occurrence (three in a row or three out of five unsatisfactory scores: Zero (0)

WTRO Report: 4th Quarter Debbie Haggard, MT Consultant/Surveyor West Tennessee Regional Office –Fourth Quarter 2020

Complaint Investigations: Zero (0)

Unsuccessful Proficiency Testing: Zero (0)

- First Occurrence (two in a row or two out of three unsatisfactory scores: Zero (0)
- Second Occurrence (three in a row or three out of five unsatisfactory scores: Zero (0)

Motion to accept the reports as given: Ms. Walton

Second: Dr. Calarco

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Danielle Gibson, MD

Yes

Jon Parham, DO

James A. Vaughn, MD

Yes

Reports were accepted as given:

Board Ratifications Initial Facility Applications:

 Parkridge North ER Laboratory 7402 Lee Highway Chattanooga, TN 37421 Specialties: Virology

Hematology Toxicology

ABO Group & Rh Type Arterial Blood Gases & pH

Gram's Stain

RSV

HCG Pregnancy Test

Streptococcus A Antigen Screen

Transfusion Service

Wet Prep

Influenza A&B Screen

Infectious Mononucleosis Screen

Routine Chemistry

Urinalysis

Laboratory Director: Lori Proctor, MD

Anatomic/Clinical Pathology

Surveyor: Fowlen Anders, MT Consultant II/ETRO

Motion: Ms. Walton Second: Dr. Parham

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Abstain
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT Yes
Keisha Burnett, SA Yes
Mark A. Calarco, DO Yes
Carla M. Davis, MD Yes
Danielle Gibson, MD Yes
Jon Parham, DO Yes
James A. Vaughn, MD Yes

The license was approved.

Other Business/Discussion:

Nothing to present.

Adjournment:

With no further business to discuss, the meeting was adjourned at 12:51 pm CST.

Motion to adjourn: Dr. Calarco

Second: Ms. Briggs

Board members responded by roll call.

LeeAnne Briggs, MT Yes
Tereyo M. Cox, MT Yes
Paul Fleming, MT Yes
Gaye G. Jolly, MT Yes

Lynn Stewart Not Present

Patti J. Walton, MT

Keisha Burnett, SA

Mark A. Calarco, DO

Carla M. Davis, MD

Danielle Gibson, MD

Yes

Jon Parham, DO

James A. Vaughn, MD

Yes

The meeting was adjourned.